Citation:

Philippou E, Neary NM, Chaudhri O, Brynes AE, Dornhorst A, Leeds AR, Hickson M, Frost GS. The effect of dietary glycemic index on weight maintenance in overweight subjects: A pilot study. *Obesity* (Silver Spring). 2009 Feb; 17 (2): 396-401. Epub 2008 Dec 4.

PubMed ID: 19057524

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the effect of altering diet glycemic index (GI) on weight-loss maintenance.

Inclusion Criteria:

- Aged 18-65 years
- Body mass index (BMI): 27-45kg/m^2
- Good health status assessed by blood tests, medical examination and electrocardiogram.

Exclusion Criteria:

Did not meet inclusion criteria.

Description of Study Protocol:

Recruitment

Conducted at the Hammersmith, Queen Charlotte's and Chelsea hospitals.

Design

- The study consisted of two parts: The weight-loss phase (first part) which was a pre-requisite for being randomized to a four-month weight maintenance phase (second part). The weight-loss phase was not randomized and aimed to achieve a 500-1,000 kcal per day deficit and a 5% reduction in body weight
- Subjects who lost at least 5% body weight, were randomized to a high-glycemic index (HGI) or low-glycemic index (LGI) diet to study the effect of diet GI manipulation on weight maintenance (second part); those that did not were dismissed from the study. During

this study phase, subjects were asked to include at least one HGI or LGICHO containing food with each of their meals and snacks. Examples of HGI foods are white or bread, cornflakes, weetabix, potatoes, couscous, melon, pineapple and rice cakes. Examples of LGI foods are seeded bread, brown pita bread, muesli, sweet potatoes, pasta, noodles, basmati slow-cook rice, beans, lentils, apples and dried fruit. Subjects were advised to eat to satisfy their appetite and follow healthy eating guidelines (e.g., avoid high-fat foods, consume five portions of fruit and vegetables).

Dietary Intake/Dietary Assessment Methodology

- Subjects were seen monthly to assess dietary compliance and anthropometrics
- Appetite was assessed bimonthly by visual analogue scales while meal challenge postprandial insulin and glucose concentrations were assessed before and after the intervention.

Blinding Used

Not applicable.

Intervention

Not applicable.

Statistical Analysis

- Only subjects who completed the whole study were considered in analysis (N=42). Data normality was tested using the Shapiro-Wilks test. Results are presented as mean ± SD or median (interquartile range). Comparisons between groups at randomization, of the activity and fitness tests and dietary intake data were done by unpaired T-tests for normally distributed data, Mann-Whitney U-tests for non-normally distributed data and x^2-tests for categorical data
- Anthropometrics, fasting blood tests and HOMA results were compared by applying linear mixed models to test the effect of diet group, time and diet group x time interaction. Postprandial glucose and insulin concentrations and VAS was compared by repeated measures ANOVA with time, diet group and visit as independent factors
- Analysis was carried out using SPSS for Windows (Version 14.0; SPSS, Chicago, IL) and results were considered significant at $P \leq 0.05$.

Data Collection Summary:

Timing of Measurements

Weight maintenance phase: Two months and four months.

Dependent Variables

Weight loss maintenance.

Independent Variables

Glycemic index.

Control Variables

None.

Description of Actual Data Sample:

- *Initial N:* 156
- *Attrition (final N):* 42
  - HGI group=19
  - LGI group=23
- *Age:* 18-65 years
- *Ethnicity:* None mentioned
- *Other relevant demographics:* None mentioned
- *Anthropometrics:* None mentioned
- *Location:* Hammersmith Hospital, London, UK.

Summary of Results:

Key Findings

- Groups did not differ in body weight
- Weight change over four months:
  - HGI: 0.3±1.9kg
  - LGI : -0.7±2.9kg
  - P=0.3.

Author Conclusion:

In the setting of a healthy eating diet, manipulating diet GI does not appear to provide a benefit for weight maintenance following weight loss.

Reviewer Comments:

None.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes

4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	N/A
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	No
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	???
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	???
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	???
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A

7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	N/A
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		???
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	No